



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of a small molecule farnesoid X receptor inhibitor

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Heliome Biotech, Inc. ("Heliome") located in New York, NY, USA.

Intellectual Property:

1. United States Provisional Patent Application No. 61/861,109, filed August 1, 2013 "Inhibitors of the Farnesoid X Receptor and Use Thereof in the Prevention of Weight Gain" [HHS Reference No. E-508-2013/0-US-01];
2. United States Provisional Patent Application No. 62/004,436, filed May 29, 2014, entitled "Methods of Treating or Preventing Obesity, Insulin Resistance and Non-Alcoholic Fatty Liver Disease" [HHS Reference No. E-508-2013/1-US-01]; and
3. PCT Patent Application No. PCT/US2014/49460 filed August 1, 2014 "Inhibitors of the Farnesoid X Receptor and Uses in Medicine" [HHS Reference No. E-508-2013/2-PCT-01].

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to make or have made, use and sell a small molecule farnesoid X receptor inhibitor for all metabolic diseases.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Thomas Clouse, J.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: thomas.clouse@nih.gov.

SUPPLEMENTARY INFORMATION: Remodeling the gut microbiota using specific compounds can affect high fat diet-induced obesity through signal transduction mediated by the nuclear receptor farnesoid X receptor (FXR). FXR is inhibited due to the altered gut microbiota as a result of lack of metabolism (bile salt hydrolase activity) of a potent FXR antagonist tauro- β -muracholic acid (T β MCA) that is produced in the liver and secreted to the intestine. The technology identifies a class of compounds that specifically decrease levels of Lactobacillus-associated bile salt hydrolase activity resulting in accumulation of intestinal T β MCA which is now identified as an antagonist of FXR. The technology has the potential of being developed into a therapeutic for various metabolic disorders associated with inhibition of the farnesoid X receptor pathway, including Non-Alcoholic Fatty Liver Disease (NAFLD), Type 2 Diabetes, and non-alcoholic steatohepatitis (NASH).

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35

U.S.C. 209 and 37 CFR Part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Date: December 15, 2015

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center, National Cancer Institute

[FR Doc. 2015-31831 Filed: 12/17/2015 8:45 am; Publication Date: 12/18/2015]